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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,744	02/02/2004	Christopher Hunter	120-000220US	4909

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EXAMINER	
WOODWARD, CHERIE MICHELLE	
ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/768,744	HUNTER ET AL.	
	Examiner	Art Unit	
	CHERIE M. WOODWARD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,11-13,18-21,24-26 and 73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,11-13,18-21,24-26 and 73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

1. Applicant's response filed 11 August 2008 is acknowledged and entered. Claims 2-5, 7-10, 14-17, 22-23, and 27-72 have been cancelled by Applicant. Claims 1, 6, 11-13, 18-21, 24-26, and 73 are pending and under examination.

Response to Arguments/Amendments

Priority/Benefit

2. Applicant argues that the examiner did not acknowledge the claim of benefit to provisional application 60/444,494, filed 31 January 2003, and provisional application 60/519,074, filed 10 November 2003 (Remarks, p. 7, fourth paragraph). **Applicant's claim for benefit** to provisional application 60/44,494, filed 31 January 2003, and provisional application 60/519,074, filed 10 November 2003, **is proper, but benefit is not accorded to the provisional filings.** Applicant's arguments appear to be identical to the arguments previously submitted on 12/13/2007.

Applicant argues that the "inventive concept" that the receptor for IL-27 is involved in the control of the duration and intensity of immune responses is provided in the second column on page 10 where "the role of IL-27R is described and proposed as a novel target for immune suppression" (Remarks, p. 7, last paragraph). Applicant argues that page 5 and pages 9-10 further describe "the discovery that the absence of IL-27R leads to immune hyperactivity" (Remarks, p. 7, last paragraph). Applicant argues that one of skill in the art would know based on the data "to activate e.g., with an agonist, IL-27R to suppress the immune system" (Remarks, p. 7, last paragraph). Applicant argues that the abstract states that the "data fully support that the receptor is an 'antagonist of T-cell mediated immune hyperactivity'" (Remarks, p. 7, last paragraph to p. 8, first paragraph). Applicant argues that the key concept embodied in the claimed invention is that activation of Il-27R can be used to suppress the immune system in contrast to the prior art's use of an agonist to activate the immune system (Remarks, p. 8, second paragraph). Applicant requests that the benefit claim be acknowledged (Remarks, p. 8, second paragraph). Applicant's arguments have been fully considered, but they are not persuasive.

As previously stated of record in the Office Action mailed 2/26/2008, neither provisional application 60/444,494, filed 31 January 2003 nor provisional application 60/519,074, filed 10 November 2003 provide sufficient support under 35 USC 112, first paragraph to enable a person of ordinary skill in the art to practice the invention claimed in the nonprovisional application. In New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co., 298 F.3d 1290, 1294, 63 USPQ2d 1843, 1846 (Fed. Cir. 2002), the court held that

for a nonprovisional application to be afforded the priority date of the provisional application, **"the specification of the provisional must contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms,' 35 U.S.C. § 112 ¶1, to enable an ordinarily skilled artisan to practice the invention claimed in the nonprovisional application."** In order for a claim in a later-filed nonprovisional application to be entitled to the benefit of the filing date of the provisional application, the written description and drawing(s) (if any) of the provisional application **must adequately support and enable the subject matter of the claim in the later-filed nonprovisional application**. If a claim in the nonprovisional application is not adequately supported by the written description and drawing(s) (if any) of the provisional application (as in New Railhead, *supra*), that claim in the nonprovisional application is **not** entitled to the benefit of the filing date of the provisional application. In order to receive benefit, the disclosure of the provisional application must adequately provides (1) a written description of the subject matter of the claim(s) at issue in the later-filed nonprovisional application, and (2) an enabling disclosure to permit one of ordinary skill in the art to make and use the claimed invention in the later-filed nonprovisional application without undue experimentation (see also MPEP 201.11, 37 CFR 1.78, and 35 USC 119(e)).

Applicant's argument that in provisional 60/44,494 the inventive concept that the receptor for IL-27 is involved in the control and duration and intensity of immune responses in mammals is taught at page 10, column 2, where the role of IL-27R is described and proposed as a target for immune suppression (Remarks. p. 8, last paragraph), is not persuasive. The only thing disclosed on page 10 is that the identification of a role for WSX-1, which is only half of the IL-27R heterodimeric receptor, comprising WSX-1 and gp130, has clinical implications for T-cell mediated disorders. No methods or steps of treating a patient or suppressing a T-helper cell mediated immune response in a patient in need thereof using an IL-27R agonist are disclosed in either provisional application.

Applicant's argument that page 5 and pages 9-10 further describe the discovery that the absence of IL-27R leads to immune hyperactivity (Remarks, p. 8, last paragraph), was previously noted, but the elucidation of one possible function for WSX-1 (which is only one subunit of the heterodimeric IL-27 receptor; the other subunit being gp130) does not provide sufficient disclosure or support for the instantly claimed method. At best it only provides motivation for future experimentation as to the monomeric subunit. Applicant's argument that one of skill in the art would know, based on the data, to activate IL-27R with an agonist to suppress the immune system (Remarks, p. 8, last paragraph) cannot be accepted in the absence of evidence. Page 10 of the 60/444,494 provisional application suggests a role for WSX-1 in the suppression of T-cell hyperactivity, but does not further expand on this unsupported hypothesis.

Nothing on page 5 nor in the abstract (page 2 of 60/444,494) nor anything in provisional application 60/519,074 provides any additional guidance in this regard. Again, at best, the provisional application suggests an opportunity for future experimentation on the monomeric subunit, but nothing more.

Merely suggesting that one of skill in the art "would know to use an agonist or activator of IL-27R suppress the immune system" based on the limited disclosure in the provisional applications is not sufficient to meet the requirements of 35 USC 112, first paragraph such that the two provisional applications may be deemed to provide sufficient support and adequate disclosure of the claims in the instant nonprovisional application. Rather, the disclosure in the provisional applications amount to nothing more than an invitation for further experimentation. Neither provisional application provides sufficient guidance or an adequate description of the genus of IL-27R agonists such that one of ordinary skill in the art would be able to make and use them in a method of treatment, as presently claimed, without undue experimentation. As such benefit to provisional application 60/44,494, filed 31 January 2003, and provisional application 60/519,074, filed 10 November 2003, is proper, but **benefit is not accorded to the provisional filings.**

Applicant continues to be accorded benefit only to the **filing date of the instant application**, that of **2 February 2004.**

Claim Objections/Rejections Maintained

Provisional Obviousness-Type Double Patenting

3. The provisional rejection of claims 1, 6, 11-13, 18-23, and 73 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-24 and 26-28 of copending Application No. 11/880,121, are maintained for the reasons of record and the reasons set forth herein. Applicant has stated that a terminal disclaimer will be submitted when all substantive issues have been resolved and the claims are otherwise in condition for allowance, if it is still necessary at that time.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 6, 11-13, 18-21, 24-26, and 73 remain rejected under 35 U.S.C. 102(a) and 35 USC 102(e) as being anticipated by Timans *et al.*, US Patent Application Publication 2002/0164609 A1 (publication date 7 November 2002) now US Patent 7,148,330 (12 December 2006, filed 30 November 2001), for the reasons of record and the reasons set forth herein.

Applicant responds to all of the rejections under 35 USC 102(a), (b), and (c) (referring to the Timans et al., publication, the DeSauvage et al., publication, the Bennett et al., publication, and the Matthews et al., patent in one responsive argument. As such, Applicant's arguments will be presented under the instant rejection over the Timans et al., reference and the arguments will not be repeated in response to the other individual rejections, below.

Applicant argues that in order to anticipate all limitations of the claims must be found in the reference or fully met by it (Remarks, p. 8, last paragraph). Applicant argues that the selecting a patient in need of immune suppression and administering an IL-27R agonist is not explicitly in the prior art (Remarks, p. 9, first paragraph). Applicant argues that the claimed invention is drawn to the treatment of a patient in need of immune suppression with an agonist of IL-27R, which is opposite to the conventional way of thinking that one should administer an antagonist to suppress immune function (Remarks, p. 9, first paragraph).

Applicant states that it was acknowledged in a telephonic interview that the prior art advocates the use of IL-27R agonists to activate the immune system and IL-27R antagonists to suppress the immune system (Remarks, p. 9, first paragraph). The examiner takes issue with the statement of Applicant's Representative because no such acknowledgement was made by the examiner. The interview summary prepared contemporaneously with the telephonic interview (mailed 8/7/2008) specifically states that that it was Applicant's representative and inventor Hunter who emphasized that the art teaches that agonists are traditionally used to activate the immune system and antagonists are traditionally used to suppress the immune system.

Applicant argues that although the class of compounds referred to as IL-27R agonists is known in the prior art, as well as the administration of such compounds to patients, the selected patient population of the claimed invention is novel over the prior art (Remarks, p. 9, first paragraph). Applicant argues that the prior art teaches that such a compound would be given to a patient in need of immune activation, not a patient in need of immune suppression, as in the claimed invention (Remarks, p. 9, first paragraph).

Applicant clarifies the record on page 9, last two paragraphs, stating that there appears to be some confusion about Applicant's acknowledgement that the term "immune disorder" includes "immune suppression" (Remarks, p. 9, last paragraph). Applicant states that the prior Office Action interprets this as an admission that "some type of immune disorder is the same as immune suppression, when in fact, immune suppression is only one species of immune disorder, another species being immune activation" (Remarks, p. 9, last paragraph). Applicant argues that when used in context, Applicant's statement was made to clarify "that although all the same terms and compositions are mentioned in the prior art, they are not combined in the same manner as claimed (Remarks, p. 9, last paragraph to p. 10, first paragraph).

Applicant argues that the claimed invention is novel over the prior art because a different patient population is treated than that contemplated in the prior art (Remarks, p. 11, second and third paragraph). Applicant argues that the claims are drawn to a new method of suppressing the immune system using IL-27R agonists (Remarks, p. 11, second paragraph). Applicant argues that to show anticipation, the examiner must show that the prior art teaches a connection between activation of IL-27R and the suppression of the immune system (as provided in the present application) (Remarks, p. 11, second paragraph). Applicant argues that this showing has not been met (Remarks, p. 11, second paragraph).

Applicant argues that the claims are patentable as a new method of using a known compound. Applicant disagrees with the examiner's reliance on *In re May and Eddy,* 197 USPQ 601 (CCPA 1978), in stating that the claimed invention is an intended use of a known compound and is not patentable(Remarks, p. 11, last paragraph). Applicant argues that the claimed invention is not a mere intended use, but rather that it is an actual method that differs from the prior art (Remarks, p. 11, last paragraph to p. 12, first paragraph). In support of this argument, Applicant cites *In re Fong, Ward, and Lundgren*, 129 USPQ 246 (CCPA 1961), holding that a new use for a known composition is patentable when directed to a process (Remarks, p. 12, third full paragraph). Applicant contrasts In re Fong with In re Pearson, 8 USPQ 641 (CCPA 1974), holding that the new use of a known compound differed only where to place the compound and thus was merely an intended use (Remarks, p. 12, last paragraph to p. 13, first paragraph). Applicant also cites *Ex parte Schundehutte and Trautner* (BPAI 1974) and *In re Paulsen* (Fed. Cir. 1994) as interpretive of the doctrine of intended use (Remarks, p. 13, last paragraph).

Applicant also refers to Chisum § 1.03[8][c] which Applicant states explains that a product or composition may not be patented for a new use of a known compound, but a process that is altered from the original process for that compound may be patented (Remarks, p. 14, first paragraph). Applicant also cites *Catalina Marketing Int'l, Inc., v. Coolsavings.com, Inc.*, 289 F.3d 801 (Fed. Cir. 2002), which discusses the principles of intended use and patenting a new use of an old compound (Remarks, p. 14, last paragraph). Applicant argues that applying the scenarios of the CAFC's hypothetical examples in *Catalina Marketing Int'l, Inc.*, to the instant case would result in the instant claims being patentable (Remarks, p. 15, second paragraph).

Applicant also argues that the claims are not inherently anticipated (Remarks, p. 15, last paragraph). Applicant argues that the step of selecting a patient in need of immune suppression and administering an IL-27R agonist to that person is not actually present or inherently present in the prior art (Remarks, p. 16, first paragraph). Applicant argues that the property of selecting a particular type of patient for receipt of the known composition is not present in the prior art inherently or in fact (Remarks, p. 16, first paragraph). Applicant argues that there is a manipulative step present in the claimed methods that is not present in the prior art and therefore the claims are not anticipated by inherency (Remarks, p. 15, first paragraph).

Applicant argues that there is a difference between recognizing a new result and taking a new action (Remarks, p. 16, second paragraph). Applicant argues that because the patient population being treated in the instant invention is different, no inherent administration of an IL-27R agonist to a person in need of immune suppression exists (Remarks, p. 16, second paragraph). In support of this argument, Applicant cites *Ansonia Brass & Co v. Electric Supply Co.*, 44 US 11 (Sup. Ct. 1892) and contrasts *General Electric v. Jewel Incandescent Lamp*, 67 USPQ 155 (Sup. Ct. 1945) and *Carnegie Steel Co., v. Cambria Iron Co.*, 185 US 403 (Sup. Ct. 1902) (Remarks, p. 16, second paragraph).

Applicant also argues that there appears to be a concern raised by the examiner that the immune suppression property of IL-27R is a natural property that is unpatentable (Remarks, p. 16, last paragraph). Applicant states that "even if, for the sake of argument, natural IL-27R agonists are considered to have an inherent ability to suppress the immune system in the body, the method as claimed is not inherently anticipated (Remarks. p. 16, last paragraph to p. 17, first paragraph). Applicant cites *In re Omeprazole Patent Litigation*, 82 USPQ 1643, at 1654 (Fed. Cir. 2007), for its holding that "[a]nticipating subject matter must be known and the knowledge must be sufficient to place enabling information in the possession of the public" (Remarks, p. 17, first paragraph). Applicant also argues the teachings of the inherency doctrine in Chisum § 3.03, and cites the example of *Glaxco Inc., v. Novopharm Ltd.*, 34

USPQ.2d 1565, at 1567 (Fed. Cir. 1995) to support the argument that no one of skill in the art would select a patient in need of immune suppression and administer an Il-27R antagonist to the patient based on what is in the prior art, individually or in combination (Remarks, p. 17, second paragraph).

Applicant's arguments have been fully considered, but they are not persuasive. One of the central themes of Applicant's arguments are that the agonism of IL-27R is counterintuitive to a person of ordinary skill in the art because conventional thinking suggests that one should administer an antagonist to suppress immune function instead of an agonist. This line of reasoning is not sufficient in the cytokine arts because of the complexity in the way cytokines regulate each other and the immune system as a whole. Applicant's analogy cannot be broadly applied to the cytokine arts because the function of each cytokine must be assessed on a case-by-case basis, based on what is known and taught in the scientific literature. Immune system function and the function of cytokines within that system is very highly regulated by a multitude of different mechanisms and cytokines may be agonistic or antagonist or both, depending on any given set of circumstances such as the particular cytokine of interest, infection, disease state (acute or chronic), humoral or cellular involvement, and if cellular involvement, the type of cells involved (B-cells, Th0, Th1, Th2, Th3, NK, CD8+, dendritic cells, neutrophils, macrophages, microglia, astrocytes, kupfer cells, etc).

The use of TNFα in the treatment of multiple sclerosis is an old and well-known example that clearly contradicts Applicant's arguments. It is generally thought by those skilled in the immunological arts that the antagonism of TNFα is a good thing because TNFα is the most well-known pro-inflammatory cytokine. However, those skilled in the cytokine arts know that in certain immune disorders, such as multiple sclerosis, antagonism of TNFα can actually exacerbate inflammatory disease. For example, Paya et al., (Int Immunol. 1990;2(9):909-13, cited for exemplary purposes only in response to Applicant's arguments) teach administration of recombinant TNFα *in vivo* to TMEV infected mice which exhibit a phenotype of CNS demyelination (abstract). TMEV mouse models are taught as being experimental models of multiple sclerosis (p. 909, column 2, last paragraph). Paya et al., teach that there is a decrease in demyelination observed when TNFα is administered *in vivo* (p. 912, column 1, last paragraph to column 2, first and second paragraphs). This means that the disease is actually treated (critical symptomology of the disease is reduced) by the administration of this "pro-inflammatory" cytokine. There is also evidence in the scientific literature that discusses the onset of multiple sclerosis associated with anti-TNFα therapy (see, for exemplary purposes only, in response to Applicant's arguments, Sicotte et al., Neurology. 27 Nov 2001;57(10):1885-8). The Paya et al., and Sicotte et al., exemplary references provide evidence that is contrary to Applicant's one-size-fits-all argument related to agonism versus

antagonism in inflammatory disease. Those skilled in the cytokine arts know and understand that not all cytokines are equal with respect to the manner in which they function to enhance or suppress an immune response.

Moreover, many cytokines have multiple regulatory functions and are considered to be pleotropic. One example is IL-6, which may be both pro-inflammatory and anti-inflammatory (see, for exemplary purposes only, in response to Applicant's arguments, Thomson et al., Eds. The Cytokine Handbook, Fourth Edition, Volume 1. Academic Press, San Diego, 2003, page 281). Another example of a pleotropic cytokine with both pro- and anti-inflammatory properties is IL-27, a member of the IL-6 family of cytokines (see, for exemplary purposes only, in response to Applicant's arguments Villarino et al., J Immunol. 2004 Jul 15;173(2):715-20. Review; and Stumhofer et al., Immunol Lett. 2008;117:123-130). IL-27 is one of the specifically recited IL-27R "agonists" of the instant claims (see instant claim 1). Those skilled in the cytokine arts would know and understand that not all cytokines are equal with respect to the manner in which they function to enhance or suppress an immune response and they would also know that some cytokines, particularly those in the IL-6 family tend to have pleotropic effects, meaning that they can function as either pro-inflammatory cytokines, enhancing an immune response, or they can be anti-inflammatory and function to suppress an inflammatory response. These extrinsic evidentiary examples show that the broad analogy used in Applicant's arguments that agonists are used to activate an immune response and antagonists are used to suppress an immune response, is not scientifically accurate as a broadly applied concept in the cytokine arts. Further, is specifically not applicable to methods of treatment involving members of the IL-6 family, including IL-27, which are well known pleotropic cytokines.

There is no requirement that a person of ordinary skill in the art would have recognized the inherent pleotropic nature of IL-27 at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."); *Abbott Labs v. Geneva Pharms., Inc.*, 182 F.3d 1315, 1319, 51 USPQ2d 1307, 1310 (Fed.Cir.1999) ("If a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale,

whether or not the parties to the transaction recognize that the product possesses the claimed characteristics."); *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1348-49 (Fed. Cir. 1999) ("Because sufficient aeration' was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of [the] invention.... An inherent structure, composition, or function is not necessarily known."); *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343-44, 74 USPQ2d 1398, 1406-07 (Fed. Cir. 2005) (holding that a prior art patent to an anhydrous form of a compound "inherently" anticipated the claimed hemihydrate form of the compound because practicing the process in the prior art to manufacture the anhydrous compound "inherently results in at least trace amounts of" the claimed hemihydrate even if the prior art did not discuss or recognize the hemihydrate). See also MPEP 2112. The fact that the Villarino et al., July 2004 review article (cited above) discusses prior art references that demonstrate the pleotropic of IL-27 and IL-27R agonists is sufficient to show the inherent nature of IL-27 to have the physical and functional property of a pleotropic cytokine - a cytokine with both pro-inflammatory and anti-inflammatory properties. As such, the inherency of IL-27 (for example), which binds to and activates IL-27R in an agonistic manner (and is a specifically recited IL-27R agonist in the claims), to act in an anti-inflammatory manner to suppress an immune response, is well established in the art, as evidenced by the scientific literature, exemplified in the Villarino et al., July 2004 review and the Stumhofer et al., extrinsic evidence references. "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill" In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). The extrinsic evidence of record and as set forth herein, clearly establishes this inherent pleotropic functionality.

Regarding Applicant's argument that there is a manipulative step present in the claimed methods that is not present in the prior art, Applicant has not shown any "manipulative step" in the claims apart from "selecting" a subject population. Applicant argues that the step of selecting a patient in need of immune suppression and administering an IL-27R agonist to that person is not actually present or inherently present in the prior art. The examiner disagrees in light of the extrinsic evidence cited above showing that IL-27 is a pleotropic cytokine, whose only known receptor is IL-27R. Because of the pleotropic nature of IL-27, its administration would inherently treat the population of patients in need of immune suppression (see also, the examiners' response to the subject population, below).

Applicant's citations of *Ansonia Brass & Co v. Electric Supply Co.*, 44 US 11 (Sup. Ct. 1892), contrasts *General Electric v. Jewel Incandescent Lamp*, 67 USPQ 155 (Sup. Ct. 1945), and *Carnegie Steel Co., v. Cambria Iron Co.*, 185 US 403 (Sup. Ct. 1902), are not on point with the facts of the instant

case because the "manipulative step" referred to by Applicant is nothing more than selecting a patient population in need of immune suppression. In the instant case, the process/method step is the same as that of the prior art - treatment of a patient population by administering an effective amount of an IL-27R agonist. The selection of the patient population is inconsequential in the instant case because the extrinsic evidence cited above clearly shows that an inherent physical and functional property of IL-27 (an IL-27R agonist) is pleotropic and that pleotropism inherently includes the suppression of an immune response.

Similarly, Applicant's citation of "*In re Omeprazole Patent Litigation*, 82 USPQ 1643, at 1654 (Fed. Cir. 2007)" [sic - the proper citation is 82 USPQ2d 1643], for its holding that "[a]nticipating subject matter must be known and the knowledge must be sufficient to place enabling information in the possession of the public" is not on point with the facts of the instant case. It is noted that the page number cited by Applicant (p. 1654) is directed to the case dissent by Judge Newman and not to the primary holding in the case. Even so, the extrinsic evidence cited above, clearly shows that the unstated limitation of the pleotropic nature of IL-27 is inherent in the methods taught in the prior art because the pleotropic nature of IL-27 is an inherent physical and functional biological property of IL-27. Stated another way, the inherent pleotropic nature of IL-27 is present in the invention taught by the prior art, as shown by the extrinsic evidence of Villarino et al., and Stumhofer et al., *supra*.

Further, Applicant's argument that no one of skill in the art would select a patient in need of immune suppression and administer an Il-27R antagonist to the patient based on what is in the prior art, individually or in combination, citing *Glaxco Inc., v. Novopharm Ltd.*, 34 USPQ.2d 1565, at 1567 (Fed. Cir. 1995), is contradicted by the numerous scientific papers cited in the Villarino et al., review article disclosing the pleotropic properties of IL-27 and specifically discussing its anti-inflammatory properties (see, i.e. Villarino et al., at p. 717; and Stumhofer et al., entire document).

Another central theme of Applicant's arguments are that the prior art does not teach a patient population in need of immune suppression such that an agonist of IL-27R may be administered to treat the population. Applicant acknowledges that the class of compounds referred to as IL-27R agonists is known in he prior art, as well as the administration of such compounds to patients (Remarks, p. 9, first paragraph). However, Applicant argues that the selected patient population is novel over the prior art. The patient population is recited in claim 1, for example, as those "in need of immune suppression." That patient population broadly includes any person or critter of any species that has any pathological disorder, trauma, or injury of any sort. Pathological disorders could include everything from atherosclerosis to a more specific autoimmune disease. Other claims narrow the population to those who have an IFNγ-mediated response that is to be suppressed (claim 13), immune hyperactivity (claim 19), and autoimmune

disorders, hypersensitivity disorders, allergies, and asthma (claim 20). Claims 21 and 73 recite broad subgeneras of inflammatory disease and a few specific species. Claims 24-26 broadly recite Th1 and Th2-mediated diseases, which are incredibly broad generas and encompass virtually every type of immune response to disease or injury. Anyone with a paper cut would fall into the patient populations of claims 1, 24, and 25. Accordingly, Applicant's argument that the claimed invention is novel over the prior art because a different patient population is treated than that contemplated in the prior art is not supported by the evidence of record or the claims, as written.

As previously stated of record, Timans et al., teach the administration of an agonist of IL-D80 [p28], IL-27, or WSX-1/TCCR, "in the treatment of abnormal medical conditions, including immune disorders, e.g…inflammation…" (p. 4, col 1, paragraph 0039). The agonists taught by Timans et al., include receptor [WSX/TCCR] agonists (p. 4, col 1, paragraph 0039), and agonists where the binding component comprises a Fv, Fab, or Fab2 fragment (p. 2, col 2, paragraph 0019). Additionally, Timans *et al.*, teach the therapeutic use of stimulatory antibodies as agonists (p. 12, col 2, paragraph 0135). Further, Timans *et al.*, teach the role of the receptor subunit WSX-1/TCCR in inflammatory responses (p. 15, col 2, paragraph 0161).

Applicant's clarifies regarding the terms "immune disorder" and "immune suppression" (discussed in the Remarks, p. 9, last paragraph) is acknowledged.

Regarding Applicant's arguments related to intended use, Applicant argues that the claimed invention is not a mere intended use, but rather that it is an actual method that differs from the prior art. Applicant cites *In re Fong, Ward, and Lundgren*, 129 USPQ 264 (CCPA 1961), and contrasts *In re Pearson*, 181 USPQ 641 (CCPA 1974) in support of this argument. Applicant also cites *Ex parte Schundehutte and Trautner* (BPAI 1974) and *In re Paulsen* (Fed. Cir. 1994) as interpretive of the doctrine of intended use, as well as Chisum § 1.03[8][c] and *Catalina Marketing Int'l, Inc., v. Coolsavings.com, Inc.*, 289 F.3d 801 (Fed. Cir. 2002), in support of the argument that an original process using a known composition may otherwise be patentable. Applicant's arguments and case law citations have been considered, but they are not persuasive.

The examiner does not dispute that in some cases the discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using (see, *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claims recite using an old composition or structure and the "use" is directed to a result or property of that composition or structure then the claim is anticipated (see *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978). In the instant case, the inherent immune suppressing physical and functional property of

IL-27, for example, as an IL-27R agonist, has been shown by the extrinsic evidence cited above. The instant claims recite using (administering) a old and well-known composition (an IL-27R agonist) and its administration is directly linked to its physical and functional property of being a pleotropic cytokine, which inherently includes immune suppression among its anti-inflammatory properties (see, i.e. Villarino et al., at 717). Because the use of the IL-27R agonist in the instant claims is directed to a property of an old and well known composition, the claims are anticipated. Additionally, the Timans et al., reference specifically recognizes the claimed result of immune suppression by administering of an agonist of IL-D80 [p28], IL-27, or WSX-1/TCCR, "in the treatment of abnormal medical conditions, including immune disorders, e.g...inflammation..." (p. 4, col 1, paragraph 0039). The agonists taught by Timans et al., include receptor [WSX/TCCR] agonists (p. 4, col 1, paragraph 0039), and agonists where the binding component comprises a Fv, Fab, or Fab2 fragment (p. 2, col 2, paragraph 0019). Additionally, Timans *et al.*, teach the therapeutic use of stimulatory antibodies as agonists (p. 12, col 2, paragraph 0135). Further, Timans *et al.*, teach the role of the receptor subunit WSX-1/TCCR in inflammatory responses (p. 15, col 2, paragraph 0161) (see *In re Tomlinson* 363 F.2d at 934, 150 USPQ 623, at 628 (CCPA 1966)).

It is noted that *In re May* and *In re Tomlinson* are precedential CCPA cases that have not been overturned or contradicted by *In re Fong, In re Pearson,* or the Federal Circuit sitting *en banc.* Moreover, *In re Fong* and *In re Pearson* are distinguishable from the present case because the issues before the CCPA in *In re Fong* related to the sufficiency of the affidavits under 37 CFR 1.131 and whether the examiner and Board had properly analyzed the claims with regard to a genus/species analysis. In *In re Pearson* the Court discussed the intended use in relation to composition claims, not method claims. Additionally, the rejection at issue in regard to the method claims was one of obviousness, not anticipation, and the Court found that a *prima facie* case of obviousness had not been established. The instant claims remain anticipated.

6. Claims 1, 6, 11-13, 18-21, 24-26, and 73 remain rejected under 35 U.S.C. 102(b) as being anticipated by DeSauvage et al., WO 01/29070 (26 April 2001) (see also US Patent Application Publication 2004/0234522 A1) for the reasons of record and for the reasons set forth below.

Applicant responds to all of the rejections under 35 USC 102(a), (b), and (e) (referring to the Timans et al., publication, the DeSauvage et al., publication, the Bennett et al., publication, and the Matthews et al., patent in one responsive argument.

Applicant's arguments with respect to DeSauvage et al., have been fully considered, but they are not persuasive. Applicant is directed to the examiner's lengthy response, set forth above. Additionally, as stated of record, DeSauvage specifically teaches methods of treatment of diseases characterized by

immune hyperactivation (see pages 59-63) using TCCR (WSX-1) polypeptides and antibodies, including agonist antibodies. Additionally, DeSauvage also specifically contemplates inhibition of molecules with proinflammatory properties (i.e. immune suppression) at p. 63, line 36. The instant claims remain anticipated.

7. Claims 1, 6, 11-13, 18-21, 24-26, and 73 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bennett et al., WO 97/25425 (17 July 1997), for the reasons of record and for the reasons set forth herein.

Applicant responds to all of the rejections under 35 USC 102(a), (b), and (e) (referring to the Timans et al., publication, the DeSauvage et al., publication, the Bennett et al., publication, and the Matthews et al., patent in one responsive argument.

Applicant's arguments with respect to Bennett et al., have been fully considered, but they are not persuasive. Bennett et al., teach methods of using the WSX-1 ligands (abstract), WSX-1 fusion proteins (p. 4) and anti-WSX-1 receptor agonist and antagonist (neutralizing) antibodies (pp. 4-5) for the treatment of hematopoietic disorders such as leukemia, lymphoma, and anemia and for enhancement of lymphopoiesis in disorders such as HIV/AIDS and infections (p. 6). Additional therapeutic uses for the WSX-1 receptor are taught on p. 41. Therapeutic uses for WSX-1 receptor ligands and antibodies are taught on pp. 56-59. The instant claims remain anticipated.

8. Claims 1, 6, 11-13, 18-21, 24-26, and 73 remain rejected under 35 U.S.C. 102(e) as being anticipated by Matthews *et al.*, US Patent 7,074,397 B1 (11 July 2006, benefit to 8 January 1996), for the reasons of record and the reasons set forth herein.

Applicant responds to all of the rejections under 35 USC 102(a), (b), and (e) (referring to the Timans et al., publication, the DeSauvage et al., publication, the Bennett et al., publication, and the Matthews et al., patent in one responsive argument.

Applicant's arguments with respect to Matthews et al., have been fully considered, but they are not persuasive. Matthews et al., teach methods of using agonist antibodies that bind to the WSX receptor (IL-27R) (column 3, lines 38-40, 46-47; column 14, lines 61-64, column 17, lines 14-16, column 44, line 22; column 80, lines 47-48 and 58-59; and column 45, beginning at line 36 to column 50) in the treatment of hematopoietic disorders, infections, and malignancies (column 50, lines 58-67 to column 51, lines 1-13). Applicant's definition of the patient population includes individuals with the same disorders taught by the '397 patent as being treatable with agonist antibodies that bind the WSX receptor (IL-27R) (see

especially, column 50, lines 58-67 to column 51, lines 1-13) (compare claims 21 and 73, especially the listed disorders of: tumor metastasis, leukemia, multiple myeloma, myelogenous leukemia, septic shock, fever, Reiter's syndrome, enteropathic arthritis, Lyme disease, staphylococcal-induced arthritis, rheumatic fever, pemphigus, and an inflammatory condition resulting from infection). The instant claims remain anticipated.

Claim Objections

9. The objection to claims 21 and 73 because the claims have multiple recitations of the same diseases and only one recitation is needed, is maintained. Although Applicant has deleted a few of the duplicate entries that were exemplified by the examiner, it is apparent that Applicant did not review the claims thoroughly for additional duplicative disorders. Duplicative disorders still recited in the claims include vasculitis. Applicant is strongly encouraged to review the claims carefully for such defects and make the appropriate corrections. Additionally, the examiner noticed that there is punctuation missing in claim 21, page 4 of 18 of the submission of 11 August 2008, line 9, following "rheumatic diseases", there is a spacing problem where no space is present between the words "induced" and "arthritis" in claim 21, page 4 of 18 of the submission of 11 August 2008, line 14. As previously stated of record, the list of disorders in claim 73 appears to be substantially duplicative of the list in claim 21 and the same duplications are also noted in claim 73. Appropriate correction is required.

Conclusion

NO CLAIM IS ALLOWED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647